Conformed Copy of Pending Claims

16. A kit of parts for use in sealing endoleaks arising from endovascular repair of an aneurysm which comprises:

(a) a fluid composition which forms a coherent mass in the presence of blood which mass adheres to the vascular surface and/or the surface of the endovascular prosthesis wherein said fluid composition comprises a biocompatible solvent and a biocompatible polymer;

(b) a catheter suitable for delivering the fluid composition to an endoleak site formed from endovascular repair of an abdominal aortic aneurysm;

(c) a catheter suitable for delivering an endovascular prosthesis to the aneurysm; and

(d) an endovascular prosthesis comprising a stent graft capable of inhibiting but not completely arresting blood flow into ~~an~~ the abdominal aortic aneurysm due to the presence of one or more endoleaks.

20. The kit of parts according to Claim 16 wherein said biocompatible polymer is selected from the group consisting of cellulose acetate polymers, ethylene vinyl alcohol copolymers and polyacrylates.

21. The kit of parts according to Claim 20 wherein said biocompatible polymer is a cellulose acetate polymer or an ethylene vinyl alcohol copolymer.

22. The kit of parts according to Claim 16 wherein said biocompatible solvent is selected from the group consisting of dimethylsulfoxide, ethanol, ethyl lactate, and acetone.

23. The kit of parts according to Claim 22 wherein said biocompatible solvent is dimethylsulfoxide.

24. The kit of parts according to Claim 16 wherein the fluid composition further comprises a contrast agent.

25. The kit of parts according to Claim 24 wherein said contrast agent is a water insoluble contrast agent.

26. The kit of parts according to Claim 25 wherein said water insoluble contrast agent is selected from the group consisting of tantalum, tantalum oxide, tungsten, and barium sulfate.

27. The kit of parts according to Claim 25 wherein said water insoluble contrast agent is characterized by having an average particle size of about 10 μm or less.

28. The kit of parts according to Claim 24 wherein said contrast agent is a water soluble contrast agent.

29. The kit of parts according to Claim 28 wherein said water soluble contrast agent is selected from the group consisting of metrizamide, iopamidol, iothalamate sodium, iodomide sodium, and meglumine.

30. The kit of parts according to Claim 24 which further comprises:

(e) a contrast agent dissolved in saline.

31. The kit of parts according to Claim 30 wherein the contrast agent is iopamidol.

32. The kit of parts according to Claim 16 wherein said one or more endoleaks arises from incomplete sealing at the interface of the aortic wall and the end of the prosthesis or from defects within the endovascular prosthesis.

Claim 30 (new): The kit of parts according to Claim 24 which further comprises:

(e) a contrast agent dissolved in saline.

Claim 31 (new): The kit of parts according to Claim 30 wherein the contrast agent is iopamidol.

Claim 32 (new). The kit of parts according to Claim 16 wherein said one or more endoleaks arises from incomplete sealing at the interface of the aortic wall and the end of the prosthesis or from defects within the endovascular prosthesis.

No new matter has been presented by these amendments. Entry of these amendments is earnestly solicited.

The amendments to Claim 16 are submitted solely to expedite the prosecution of what is believed to be allowable subject matter. Applications specifically reserve the right to file one or more continuation applications directed to the subject matter of the previously presented claims.

For the convenience of the Office, a conformed copy of the now pending claims is attached.

Rejection under 35 U.S.C. §103(a)

Claims 16 and 20-29 stand rejected under 35 U.S.C. §103(a) over McCrory, U.S. Patent No. 5,951,599, in view of Chuter, et al., *J. Vasc. Surg.* 2000, 31: 122-133, May, et al., *J. Vasc. Surg.* 2000, 32: 124-129, and Evans, et al., U.S. Patent No. 5,695,480.[2] For the following reasons, this rejection is traversed.

The test for non-obviousness articulated by the Court of Appeals for the Federal Circuit in *In re Vaeck* requires consideration of at least the following factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should practice the claimed invention; and (2) whether the prior art would also have provided a reasonable expectation of success to such a skilled artisan. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The first requirement goes to the question of motivation, and refers to a line of well established cases that there must be some logical reason at the time of the invention for modifying the cited references along the lines of the invention; otherwise the use of the teachings as evidence of non-obviousness will entail prohibited hindsight. *Ex parte Stauber and Eberle*, 208 USPQ 945 (Bd. App., 1980).

---

[2] Applicants note that both the Chuter and May references were published after the initial priority date for this application (March 1999). To the extent that these references are distinguished herein, Applicants merely reserve the right to remove these references based on the after filing publication date.

Applicants maintain that a *prima facie* case of obviousness has not been established because there is no suggestion or motivation, outside Applicants' own disclosure, to modify the cited art in a manner necessary to arrive at the claimed invention. Nor is there any reasonable basis in the art to reasonably expect that the prior art, so modified, would provide for efficacious results demonstrated by the claimed invention.

As to the claimed invention, in its broadest aspect, it is directed to a kit of parts comprising the following components:

(a) a fluid composition which forms a coherent mass in the presence of blood which mass adheres to the vascular surface and/or the surface of the endovascular prosthesis wherein said fluid composition comprises a biocompatible solvent and a biocompatible polymer;

(b) a catheter suitable for delivering the fluid composition to an endoleak site formed from endovascular repair of an abdominal aortic aneurysm;

(c) a catheter suitable for delivering an endovascular prosthesis to the aneurysm; and

(d) an endovascular prosthesis comprising a stent graft capable of inhibiting but not completely arresting blood flow into the abdominal aortic aneurysm due to the presence of one or more endoleaks.

The kit is designed for use by a physician in sealing endoleaks within a stent graft during placement of the graft intra-arterially at the site of an abdominal aortic aneurysm. Central to this concept is the recitation that the endovascular prosthesis comprising a stent graft capable of inhibiting but not completely arresting blood flow into the abdominal aortic aneurysm due to the presence of one or more endoleaks.

New Claims 30 and 31 elaborate upon this concept by including in the kit a solution of saline comprising a contrast agent for use in determining the integrity of endoleak repair.

The McCrory reference is directed to the treatment of aneurysms using a stent delivered to the aneurysmal site via a catheter. The stent disclosed by McCrory is either initially or subsequently engineered to contain a first portion and a second portion wherein the first portion is permeable to blood flow whereas the second portion is less permeable to blood flow such that when used *in vivo*, the hemodynamics of the system are altered such that flow does not, in any meaningful quantity, enter the aneurysmal sac.[3]

As correctly noted in the Office Action, McCrory fails to disclose the use of a stent graft but, rather, is limited to the disclosure of stents. Moreover, McCrory is neither concerned with endoleak nor with endoleak repair. In fact, the McCrory device is taught as not allowing any meaningful blood flow into the aneurysmal sac after deployment and, accordingly, based or her own teachings, the disclosed device cannot exhibit endoleaks.

Contrarily, the now claimed invention recites an endovascular prosthesis comprising a stent graft capable of inhibiting but not completely arresting blood flow into the abdominal aortic aneurysm due to the presence of one or more endoleaks. Claim 32 elaborates upon this by reciting that the endoleak arises from incomplete sealing at the interface of the aortic wall and the end of the prosthesis or from defects within the endovascular prosthesis. In any event, this distinction is one of substance because endoleaks repair in an abdominal aortic aneurysm treated with a stent graft necessitates that the stent graft was not capable of completely arresting blood flow into the aneurysm. Contrarily, the McCrory recites that her device accomplishes just the opposite.

Accordingly, standing alone, the McCrory reference cannot obviate the now claimed invention.

As to the secondary references, there is simply no motivation in these references to modify the teachings of McCrory in the manner necessary to arrive at the now claimed invention.

---

[3] See, for example, Col. 2, lines 6-12, of McCrory.

As to these secondary references, the Office Action alleges that they teach that stents and stent grafts are equivalent in treating abdominal aortic aneurysms.[4] Applicants take issue with this allegation. First, Chuter, in the section starting at page 123 entitled "Device description" describes all of the devices employed in his study as "stent grafts". Nowhere does Chuter disclose the use of stents in treating abdominal aortic aneurysms.

As to May, this reference recites that the first and second generation devices used for treating abdominal aortic aneurysms differ by virtue of a one-piece construction (first generation) or modular construction (second generation).[5] Applicants have found no statement in May that the first generation prosthesis is a stent. Rather, Table III cited in the Office Action references a Chuter prosthesis which, if this prosthesis is the same as that of the Chuter reference, it is a stent graft. Accordingly, any assertion in the Office Action to this effect is reading more into the reference then it teaches and Applicants maintain that such a characterization is improper.

Notwithstanding the above and assuming *arguendo* that the allegation of equivalence between stents and stent grafts made in the Office Action and based on May and Chuter is, in fact, correct, such equivalence in treating abdominal aortic aneurysms by itself is insufficient to obviate the claimed invention.

In regard to the above, the mere fact that the now claimed invention is directed to kit of parts does not negate the requirements that 35 U.S.C. §103(a) still requires motivation in the cited references *and not from Applicants' own teachings,* to arrive at the claimed invention. As to this issue, the McCrory stent is disclosed for use with aneurysms including abdominal aortic aneurysms.[6]

---

[4] See page 3, last full paragraph o f the Office Action.

[5] Abstract, fourth sentence in the Methods section.

[6] See, for example, Col. 4, lines 1-3, of the McCrory reference. Any statements made heretofore in the prosecution that McCrory teaches otherwise are expressly withdrawn.

Accordingly, there can be no motivation to substitute the stent in McCrory with a stent graft taught in the Chuter and May references since McCrory's stent already fulfills the very function required by the substitution. Moreover, even if one assumes that the stents of McCrory are equivalent to the graft stents of Chuter and May, there is simply no teaching that such equivalence carries over to use of an embolic materials in combination with such stents. For example, McCrory teaches several examples of where an embolic composition is delivered through the stent matrix into the aneursymal sac.[7] Contrarily, as noted in the declaration of Richard Greff,[8] vascular grafts (stent grafts) are closed or impermeable devices which could not allow delivery of an embolic composition in the manner taught by McCrory since such delivery would require rupture of the device. Under such circumstances, the graft stents of Chuter and May are not interchangeable with those of McCrory and, in fact, the skilled artisan would be lead to the conclusion that interchangeability in contra-indicated because puncture of the stent graft could create blood flow (e.g., an endoleak) into the abdominal aortic aneurysm.[9]

McCrory further teaches that the aneurysmal sac may first be filled with the embolic material prior to insertion of the stent[10] which is preferably a shape memory alloy. Such prior delivery of the embolic material does not make her stents interchangeable with graft stents because of the unpredictability of the effects the embolic materials may have on graft stents. As noted in the declaration of Richard J. Greff, *supra.*, graft stents are made of natural or synthetic materials which, unlike metals, may or may not be compatible with the embolic material used by McCrory. For example, a solvent used in a polymer solution could dissolve a natural or synthetic material but not a metal.[11] Further in this regard, reference is made to page 125 of Chutter wherein endoleaks are

---

7 See, for example, Figures 3A and 4B of McCrory as well as Col. 5, lines 25-35.

8 Declaration of Richard J. Greff Pursuant to 37 C.F.R. §1.132 filed with the response of January 22, 2003.

9 See, for example, the paragraph bridging pages 128-129 of Chutter, et al. wherein small or large holes in the stent graft are characterized as type III or IV endoleaks.

10 See, for example, Col. 4, lines 52-54, of the McCrory reference.

repaired with either additional stent grafts or coils. No reference is made therein to the use of fluid compositions.

In view of the above, the allegation in the Office Action that McCrory's stents are interchangeable with stent grafts of the prior art as exemplified by Chuter and May misses the point. That is to say that interchangeability can not be assumed in a vacuum but rather must be evaluated in the field of intended use and, as shown above, when so viewed, there is no interchangeability.

Applicants submit that substitution of the stent graft for McCrory's stent in the Office Action is apparently predicated on the need to arrive at Applicants' claimed combination of components and not based on the cited art *per se.* Such is an impermissible use of Applicants' own teachings because the use of a embolic material with other than a stent is not fairly based on the prior art but, in fact, taught away from.

In view of the above, withdrawal of this rejection is requested.

Applicants submit that this application is now in condition for allowance. A notice to that effect is earnestly solicited.

If it is determined that a telephone conversation would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

---

[11] If the stent graft is inserted prior to curing of the polymer solution, solvent dissipating from the aneurysmal sac may adversely affect the integrity of the natural or synthetic material.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2859** referencing docket no. 554922004910.

Dated: January 20, 2004

Respectfully submitted,

By Gerald F. Swiss

Gerald F. Swiss
Registration No.: 30,113
Swiss Law Group
Building 3, Palo Alto Square
3000 El Camino Real, Suite 100
Palo Alto, CA 94306
650-856-3700
Attorneys for Applicants